

K960407



APR 26 1996

CONTACT PERSON : MR. Y.W. CHOW  
WEMBLEY RUBBER PRODUCTS  
(M) SDN BHD

Lot 1, Jalan 3  
Kawasan Perusahaan Bandar Baru  
Salak Tinggi, 43900 Sepang,  
Selangor, Malaysia.  
Corporate Office Tel: 8461486  
8461867  
Fax: 8461485  
8461557  
Factory Office: 8461495  
8461496  
Fax: 8461488  
8461608

### 510 (K) SUMMARY

1. Trade Name : COMFIT ORTHOPAEDIC, BROWN BEADED  
SURGEON'S GLOVES (POWDERED,  
HYPOALLERGENIC)
2. Common Name : Surgeon Gloves
3. Classification Name : Surgeon Glove
4. Substantial Equivalence :

Class I natural rubber latex surgeon glove, 79 KGO, powdered with absorbable dusting powder, hypoallergenic, that meets all of the requirements of ASTM standard D3577-91.

5. Description of device :

Class I natural rubber latex surgeon glove, 79 KGO, powdered with absorbable dusting powder, hypoallergenic, that meets all of the requirements of ASTM standard D3577-91.

COMFIT ORTHOPAEDIC brown surgical gloves are 0.30 mm (minimum) thick single wall at finger and palm areas to reduce damage from contacting bone, screws, wires or instruments.

6. Intended use of device :

The gloves are intended to be worn on the hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment.

# 7. Summary of Performance data :

Performance data of gloves to ASTM D 3577-91 and FDA 1000 ml watertight test.

TEST	ASTM D 3577-91	COMFIT ORTHOPAEDIC Brown Beaded Surgeon's Gloves (Powdered, Hypo)
1. Watertight (1000 ml)	S-4, AQL 1.5	Pass based on AQL of 1.0
2. Length (mm)		
Size 5.5	min 245	260
6.0	min 265	265
6.5	min 265	265
7.0	min 265	270
7.5	min 265	293
8.0	min 265	293
8.5	min 265	293
9.0	min 265	293
3. Palm width (mm)		
Size 5.5	70 ± 6	72
6.0	76 ± 6	77
6.5	83 ± 6	83
7.0	89 ± 6	89
7.5	95 ± 6	94
8.0	102 ± 6	102
8.5	108 ± 6	108
9.0	114 ± 6	114
4. Thickness (mm)		
Finger	min 0.10	0.36
Palm	min 0.10	0.31
5. Physical Properties		
<u>Before Ageing :</u>		
Tensile Strength (MPa)	min 24	29.29
Ultimate Elongation (%)	min 750	890
<u>After Ageing :</u>		
Tensile Strength (MPa)	min 18	28.38
Ultimate Elongation (%)	min 560	852

**6. Substantial Equivalence based on assessment of Non-Clinical performance data**

The performance test data of device as shown above indicate that this glove meets requirements of ASTM D 3577-91.

**7. Assessment of Clinical Performance data**

Clinical data of 200 Human Subjects on Modified Draize test done on this glove demonstrated no potential for eliciting either dermal irritation or sensitization and support the labeling claim for "hypoallergenic".

**8. Conclusion**

This glove exceed the ASTM D 3577-91 requirements, meet pinhole FDA requirements , meet Hypoallergenic labeling claim.

Date Summary Prepared : January 20, 1996